IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	St Goar *et al.*
Serial No.:	10/635,776
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For:	*METHODS AND APPARATUS FOR CARDIAC VALVE REPAIR*
Art Unit:	3734
Examiner:	Bachman

Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF TROY L. THORNTON UNDER 37 C.F.R. §1.132

I, TROY L. THORNTON, do hereby declare as follows:

1. I am Vice President of Research and Development for Evalve, Inc. ("Evalve"), assignee of the above-captioned patent application, U.S. Application Serial No. 10/635,776 ("the '776 application"). I received a B.S. in Engineering Science with Biomedical Engineering emphasis in 1985 from Iowa State University, Ames, IA. I have over 23 years of experience developing cardiovascular devices, implants and delivery systems. I am an inventor of 36 patents/patent publications. Since July 2000, I have managed all research and development activities for Evalve relating to cardiovascular device implants and delivery systems. A copy of my curriculum vitae is attached hereto as Exhibit 1.

The '776 Application

2. I have reviewed the '776 application, including pending claims 1, 8, 10-12, 14-18, 43, and 51-65.

3. I am aware of the U.S. Patent Office rejection of claims 1, 8, 10, 12, 14-18, and 62-65 of the '776 application under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,269,819 to Oz (the "Oz patent") in view of U.S. Patent No. 6,165,183 to Kuehn (the "Kuehn patent.") In fact, Evalve is a licensee of the Oz patent in question.

4. I am also aware of the rejection of claim 11 under 35 U.S.C. §103(a) as being unpatentable over the Oz patent in view of U.S. Patent No. 5,450,860 to O'Connor (the "O'Connor patent"). I have reviewed the Oz patent, the Kuehn patent, and the O'Connor patent.

5. Based on my education and industry experience, I am familiar with the level of skill of one of ordinary skill in the art at the time of the invention of the '776 application.

6. The Oz patent describes an apparatus for use in heart valve repair involving the use of an inserted device for grabbing and clasping together the anterior and posterior leaflets of the heart valve. [Oz, 2:33-36.] The device includes jaws that deploy directly on the mobile, free edge of the leaflets and clamp them together to cause the opposing edges of the leaflets to come together. The jaws affix a closure device directly onto the free edge of the opposing anterior and posterior leaflets to secure the free edge of each leaflet to one another. [Oz, 4:32-38; Figures 1-4.]

7. It is my expert opinion that the embodiments disclosed in the Oz patent are designed specifically for deployment on free edges of the leaflets. In fact, Evalve has developed a commercial product (a clip placed onto the opposing free edge of the leaflets) based in part on Oz's teachings.

8. Valve leaflets are thin, pliable, mobile and readily conformable. The valve annulus is muscular, significantly thicker and less compliant than the leaflets. Moreover, leaflets are generally planar whereas the annulus is generally considered a muscular ring. A portion of the leaflets are connected to the annular ring, but the free edges are not. The free edges open during ventricular diastole, then close against each other during ventricular systole.

9. The approach disclosed in the Oz patent treats mitral regurgitation by affixing the mobile portion (free edge) of one leaflet to the other, whereas the approach disclosed in the claimed invention modifies the structure of the annulus. These are two completely different approaches which entail a different set of engineering requirements. In other words, an Oz device which affixes thin, planar leaflets together is not capable of gathering together the tough non-planar, muscular annulus to affect a change in the annular length.

10. It is my expert opinion that the embodiments described in the Oz patent would need to be completely redesigned to "adapt" them for deployment at a tissue location directly on the annulus rather than on leaflets connected to the annulus.

11. It is my expert opinion that there is no motivation or suggestion in the Oz patent to modify the Oz apparatus so that it could be deployed directly on the annulus.

12. It would have been beyond the level of ordinary skill in the art at the time of the invention to modify the Oz apparatus for deployment directly on the annulus.

13. Even if one of ordinary skill in the art were motivated to modify the Oz apparatus to be capable of deployment directly on the annulus, the modifications necessary to adapt the Oz apparatus for deployment directly on the annulus would not have been obvious to one of ordinary skill in the art at the time of the invention.

14. The Oz apparatus would require significant engineering modifications in order to enable the apparatus to be deployed directly on the annulus, even moreso, for the apparatus to 'gather together' any significant amount of annular tissue in order to effect any a change in the length of the annular ring of muscle . Such engineering modifications were non-obvious to one of ordinary skill in the art at the time of the invention. Furthermore, there is no motivation or suggestion to make such modifications to the Oz apparatus in either the Oz patent or the Kuehn patent.

15. The Kuehn patent describes various devices and methods for fastening and securing thin planar tissue segments (e.g., leaflets) to one another.

16. FIGs. 1-7 of Kuehn illustrate a suture line attached to the free edge of the leaflets. Kuehn does not disclose or suggest a catheter device for attaching the suture to the edge of the leaflet. Namely, a catheter device which captures and

supports the leaflets as the needle (used to thread the suture) pierces the leaflets. Similarly, Kuehn does not disclose or suggest a catheter device for deploying a supporting structure directly on the annulus.

17. FIGs. 8-12 of Kuehn illustrate a barbed needle or staple which has pierced the free edge of the valve leaflets. Kuehn does not disclose or suggest a catheter device for attaching the barbed needle to the edge of the leaflet. Namely, a catheter device which captures and supports the leaflets as the barbed needle pierces the leaflets. Similarly, Kuehn does not disclose or suggest a catheter device for deploying a supporting structure directly on the annulus.

18. FIGs. 13A-13F of Kuehn illustrate a pair of wire–like spring clips 262. As best as can be determined, the clips self-expand when freed from the constraint imposed by the sleeve 254. These clips are configured to secure planar tissue segments with a portion of the clip on either side of the planar tissue segment. See FIG. 13B. The disclosed apparatus would not be suitable for modifying the annulus which has a different anatomy than the leaflets. The annulus is not planar and consequently it would not be possible, in my opinion, to place the clips on either side of the annulus so as to reduce regurgitation between the leaflets.

19. FIGs. 14A-14D of Kuehn illustrate another spring clip design. As best as can be determined, the arms of the clip self-expand when freed from the constraint imposed by the sleeve. These clips are configured to secure planar tissue segments with a portion of the clip on either side of the planar tissue segment. See FIG. 14C. The disclosed apparatus would not be suitable for modifying the annulus which has a different anatomy than the leaflets. The annulus

is not planar and consequently it would not, in my expert opinion, be possible to place the clips on either side of the annulus so as to reduce regurgitation between the leaflets.

20. FIGs. 15, 16, 23 and 24 show a spiral needle/wire between two leaflets. This device is configured to pull opposing planar tissue segments into apposition using suction and then the spiral needle is threaded through the segments and left in place. The disclosed apparatus would not be suitable for modifying the annulus which has a different anatomy than the leaflets. The annulus is not planar and there are not two or more segments between which to insert the device. In my expert opinion, it would not be possible to use this device to modify the valve annulus so as to reduce regurgitation between the leaflets.

21. FIGs. 17 – 19D illustrate a device purportedly used to affix a tack to leaflets. It is not clear how the device could be delivered via a catheter and positioned to capture leaflets let alone the annulus. The device is configured to affix a tack through a planar tissue segment. In my expert opinion even if the device shown in FIG. 15 could be delivered via catheter and somehow affix a tack to the annulus, the device still would not be capable of modifying the annulus so as to reduce regurgitation between the leaflets.

22. FIGs. 20-21 show a grasping device which like all of the other embodiments purports to be useful for grasping and affixing planar tissue segments. Here the device is inserted so that graspers sandwich the planar tissue segments from above and below. It is not clear how leaflets could be affixed with

this device in place. In my expert opinion, this device would not be suitable for grasping or modifying non-planar tissue such as the valve annulus.

23. FIGs. 25-31 illustrate a two-piece plate apparatus useful for securing planar tissue segments. The two pieces of the plate sandwich the top and bottom portions of the planar tissue segments. In my expert opinion this device would not be suitable for grasping or modifying non-planar tissue such as the valve annulus, and would not be capable of modifying the annulus so as to reduce regurgitation between the leaflets.

24. FIGs. 33-44 show a spring clip useful on a planar tissue member. The clip 640 has two sharp ends 632 and 634 which are supposed to penetrate the planar tissue segments. It is not clear how the device holds the leaflets while the sharp ends pierce the leaflets. I have grave reservations whether the disclosure is enabling for its intended purpose of securing valve leaflets. Moreover, in my expert opinion this device would not be suitable for grasping or modifying non-planar tissue such as the valve annulus and would not be capable of modifying the annulus so as to reduce regurgitation between the leaflets.

25. It is my expert opinion that none of the devices described in the Kuehn patent are adapted for deployment at a tissue location directly on the annulus rather than on leaflets connected to the annulus. Rather, the devices are adapted for deployment only on the valve leaflets, specifically on the mobile, free edges of the leaflets. Even if the devices were capable of being deployed directly on the annulus, they would not be capable of modifying the annulus so as to reduce regurgitation between the leaflets

26. It is my expert opinion that there is no motivation or suggestion to modify the Kuehn devices so that the devices could be deployed directly on the annulus. Even if one of ordinary skill in the art were motivated to modify the Kuehn devices for deployment directly on the annulus, the modifications necessary to adapt the Kuehn devices for deployment directly on the annulus would not have been obvious to one of ordinary skill in the art at the time of the invention. The Kuehn patent provides insufficient detail to enable or motivate one of ordinary skill in the art to modify the Kuehn devices or the Oz apparatus for deployment directly on the annulus.

27. The O'Connor patent describes a non-catheter based annuloplasty procedure where the mitral valve is exposed by a left atriotomy. In my expert opinion, there would be no motivation at the time of the invention to combine the non-catheter based, surgical procedure of O'Connor with the catheter-based apparatus described in Oz. Even if such motivation were present, it would be beyond the level of skill of one of ordinary skill in the art to modify the Oz apparatus to circumferentially shorten the annulus based on the teachings of the O'Connor patent.

28. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

7/31/09
Date

Troy L. Thornton

EXHIBIT 1 OF DECLARATION OF TROY L. THORNTON UNDER 37 C.F.R. 1.132

TROY L. THORNTON
743 Carolina St. San Francisco, CA 94107
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SUMMARY: **Results-oriented R&D leader with over 20 years of cardiovascular device design, development and management experience, including clinical training and support.**

PROFESSIONAL EXPERIENCE:

June 2000 – Present: Vice President, Research & Development, Evalve, Inc., Redwood City, California

Responsible for managing all aspects of research and development for a novel cardiovascular device implant and delivery system.

Included physician training, field clinical support, Clinical Specialist support and analysis of clinical results.

June 1995 – May 2000: Project Manager, Prograft Medical, Inc. (1997 acquired by W.L Gore & Associates, Inc.) Sunnyvale, Calif.

Responsible for development and successful commercial introduction of a bifurcated, modular stent-graft used in the treatment of abdominal aortic aneurysms.

- Designed and built the first prototypes, conducted acute and long-term animal studies, and managed the overall project from inception through initial commercialization (outside U.S.).
- Hired and managed a team of six engineers and three technicians.
- Worked closely with clinical and regulatory departments in writing IDE filings, instructions for use, and clinical protocols.
- Developed physician and in-house training materials. Trained Gore clinical specialists and sales associates worldwide.
- Provided physician training and case support during the U.S. IDE trial.
- Supported physicians during five live case transmissions at endovascular symposia worldwide.
- *Result was exponential growth of implants from 140 in 1998 to 600+ in 1999 with total sales generated of over $5 million prior to initial market release. Product reached $100+ mil. in sales within 2 yrs of FDA approval.*

August 1989 – 1995 May: Project Group Leader, Senior Engineer for Advanced Cardiovascular Systems (Guidant), Santa Clara, CA.

1993 – 1995: Project Group Leader, Perfusion PTCA Catheters

- Responsible for conceiving, prototyping, and testing innovative coronary perfusion catheter concepts. Proved feasibility, and filed two patents relating to the most promising concepts.

1989 – 1993: Senior R&D Engineer, Rapid Exchange PTCA Catheters

- Developed an elliptical coronary PTCA catheter from initial concept to market launch. Responsible for catheter design, material selection, process development, performance teseting, physician evaluation, and animal studies.
- Direct supervision of two engineers and two technicians. Managed a large project team which finalized development and implemented the design in full-scale manufacturing.
- The catheter gained 20 market share points, and became the top-selling PTCA in the U.S. with over $60 million / year in sales.

1987 – 1989: Manufacturing Engineer, Symbion, Inc., Salt Lake City, UT

Developed and improved processes for class III medical device product lines. Developed ultrasonic welding processes for four parts of a centrifugal blood pump. Designed packaging, validated sterilization, and designed/installed a new clean room.

1985 – 1987: Process Engineer, Becton-Dickinson, Inc., Sandy, UT

Validated processes and implemented into pilot manufacturing a thermodilution catheter. Conducted cost-saving programs and process improvements on central venous catheter products.

EDUCATION: B.S. Engineering Science with Biomedical Engineering emphasis, 1985 Iowa State University, Ames, IA

PATENTS: Thirteen issued patents; 12+ patents pending